



**US Environmental Protection Agency
Office of Pesticide Programs**

Petition for Indoxacarb

October 16, 2007



DuPont Crop Protection
Stine-Haskell Research Center
P.O. Box 30
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October 16, 2007

DELIVERED BY COURIER SERVICE

Document Processing Desk – (REGFEE)
Attn: John Hebert
Office of Pesticide Programs (7504P)
U. S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Subject: Request for Extension of Exclusive Use Period for Products Containing
Indoxacarb Per FIFRA §3(c)(1)(F)(ii)

Dear John:

On October 30, 2000, EPA granted the first registrations for products containing indoxacarb as the active ingredient, including DuPont™ Avaunt® and DuPont™ Steward® Insecticides (EPA Reg. Nos. 352-597 and 352-598). In 1996, the Food Quality Protection Act (FQPA) became law. This act included a provision which states “The period of exclusive use... shall be extended 1 additional year for each 3 minor uses registered after the date of enactment of this clause and within 7 years of the commencement of the exclusive use period, up to a total of 3 additional years for all minor uses registered by the Administrator...” “Minor Uses” are defined in FIFRA (§ 2(II)(2)) as meeting one of 4 criteria:

1. There are insufficient efficacious alternative registered pesticides available for the use,
2. The alternatives to the minor use pesticide pose greater risks to the environment or human health
3. The minor use pesticide plays or will play a significant part in managing pest resistance, or
4. The minor use pesticide plays or will play a significant part in an integrated pest management program.

The exclusive use provision for minor uses provision of FIFRA §3(c)(1)(F)(ii) contains these identical criteria, i.e. – a use identified as a minor use under FIFRA § 2(II)(2) meets at least one of these 4 criteria.

DuPont hereby requests the Agency to approve an extension of the exclusive use period for an additional 3 years based on the following information:

Crops Submitted As Part of the Initial Registration

- DuPont received Reduced Risk classification for all proposed uses as part of the original submission (see Tab 1 in the Supporting Information volume which accompanies this letter)
- DuPont supplied residue data for 9 minor crops as part of the original submission. These include:
 - Cabbage, ✓
 - Broccoli, ✓
 - Tomatoes, ✓
 - Peppers, ✓
 - Head lettuce, ✓
 - Leaf lettuce, ✓
 - Apples, ✓
 - Pears and ✓
 - Sweet corn ✓
- Criterion 2 (above) is fulfilled for all 9 crops since these minor crops were all classified as "Reduced Risk" and indoxacarb was identified as an alternative to organophosphate pesticides as part of that action (see highlighted section on page 4 of Tab 2 in the Supporting Information volume which accompanies this letter - "U.S. EPA, Office of Pesticide Programs, Reduced Risk/Organophosphate Alternative Decisions for Conventional Pesticides, updated 8/10/07, (<http://www.epa.gov/opprd001/workplan/completionsportrait.pdf>),).

Crops Submitted Subsequently

- Subsequent to the initial registration, the IR-4 Program has submitted tolerance petitions for indoxacarb on numerous minor crops since the initial registration. Residue data, jointly developed by DuPont and IR-4, were submitted for the following 13 crops:
 - Mint
 - Southern pea
 - Cranberry
 - Mustard greens
 - Plum
 - Peach
 - Cherry, sweet
 - Cherry, sour
 - Summer squash
 - Cucumber
 - Cantaloupe

- Spinach
- Celery

The Agency has recently established tolerances based upon these data (72 FR 37633 - 37641, July 11, 2007).

All Crops on Indoxacarb Product Labels

- Because of the need for indoxacarb as an alternative insecticide on these and other minor use crops, IR-4 requested that DuPont consider labeling of crop groups resulting in additional uses on the indoxacarb product labels. IR-4 collaborated with DuPont in the submissions which resulted in EPA approvals. Current crop groups on the indoxacarb label include, brassica leafy vegetables, cucurbit vegetables, leafy green vegetables, leafy petiole vegetables, pome fruit, stone fruit and tuberous and corm vegetables.
- By virtue of the fact that the IR-4 program - whose Mission is to "provide pest management solutions to growers of fruits, vegetables and other minor use crops" was involved with these minor use registrations means that these crops clearly meet the definition of "minor uses" as defined by FIFRA § 2(II). In other words, registration of a minor use for a pesticide should be sufficient to establish that at least one of these 4 criteria have been met for that use.
- The website for the Regional Integrated Pest Management (IPM) Centers (established by the Cooperative State Research, Education, and Extension Service, United States Department of Agriculture) references indoxacarb as an important tool to be used for insect control as part of IPM programs for all crops labeled prior to the recent tolerance approvals (see enclosed printout of National Information System for the Regional IPM Centers); several printouts showing the importance of indoxacarb in IPM programs are also enclosed.
(See http://www.ipmcenters.org/cropprofiles/cp_form.cfm and search for "indoxacarb") These documents support the vital role indoxacarb plays in an effective IPM program (Criteria 4) (See highlighted information in Tabs 4 - 8 in the Supporting Information volume which accompanies this letter .
- In 2002 a Section 18 emergency exemption was granted for use of indoxacarb on cranberries in Massachusetts. In 2003 a Section 18 emergency exemption was granted for use of indoxacarb on collards in Georgia. In both cases the Section 18 requests were renewed over several consecutive years. This clearly displays that use of indoxacarb on these 2 minor crops provided efficacious insect control that was not currently available in the marketplace. (Criteria 1)

- In 2003 an Experimental Use Permit was granted for the use of indoxacarb in stone fruit. This EUP was sponsored by the EPA, USDA's Risk Avoidance and Mitigation Program (RAMP) and DuPont. The EUP was administered by several leading stone fruit University researchers. The goal of the RAMP is to enhance development and implementation of innovative integrated pest management strategies for multi-crop food production systems. The primary emphasis of RAMP applications is crop productivity and profitability while addressing critical environmental quality and human health issues. As demonstrated in the EUP report, indoxacarb met the criteria set forth by the RAMP effort. Indoxacarb is clearly a helpful tool in an IPM program in stone fruit. This meets the requirements set forth in Criteria 4.
- The California Department of Pesticide Regulation has recently issued a document entitled "ENVIRONMENTAL FATE OF INDOXACARB" (copy enclosed). In part, the document states:

"Indoxacarb, a broad spectrum foliar insecticide, is registered for use on a broad range of crops, which include fruits (apples, pears, and tomatoes), vegetables (bok choy, broccoli, Brussels sprouts, cabbage, cauliflower, Chinese cabbage, corn, eggplant, kohlrabi, peas, peppers, potatoes, and lettuce), soybeans, alfalfa, and cotton. It controls or suppresses many insects, including beet armyworm, cabbage looper, corn earworm, diamondback moth, fall armyworm, imported cabbageworm, southern armyworm, tomato pinworm, and tomato fruitworm (DuPont, 2006; California Department of Pesticide Regulation, 2006).

"Many insects have developed resistance to conventional pesticide chemistries, such as organophosphates, carbamates, and pyrethroids. To combat these pesticide resistant pests new chemistries have been developed with novel modes of action unrelated to previous chemical classes to replace the old chemistries. Indoxacarb is a non-systemic, synthetic organophosphate replacement insecticide that has good field activity against a number of Lepidoptera pests, as well as certain Homoptera and Coleoptera pests."

This passage supports criteria 3 & 4, above.

The provision for the extension of the exclusive use period in the Food Quality Protection Act "was intended to be an incentive for registering more minor uses." ("Report on Minor Uses of Pesticides", EPA's Minor Use Team and Public Health Steering Committee in cooperation with the United States Department of Agriculture, October 9, 2001). DuPont has pursued minor crop uses in cooperation with the IR-4

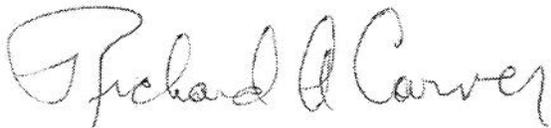
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program with the understanding that the Agency would deliver on the promise made in this statute.

Based on the evidence outlined above for meeting the criteria outlined in the FQPA registration of minor use provision, DuPont Crop Protection requests an additional 3 years of exclusive use for the data supporting indoxacarb registrations.

Please contact me at 302-451-4517 if you have any questions regarding this request.

Sincerely,

A handwritten signature in cursive script that reads "Richard A. Carver". The signature is written in dark ink and is positioned above the printed name and title.

Richard A. Carver, Ph.D.
Sr. Product Registration Manager